Provider Newsflash
October, 2021

Company Announcement/Recall – Aligned Medical Solutions/Cardinal Health Monoject Syringes

Purpose of this communication:

We are writing to inform you that the FDA has posted a voluntary nationwide recall by Windstone Medical Packaging dba Aligned Medical Solutions of Cardinal Health's Monoject Flush Prefilled Saline Syringes part #8881570121 that was placed into their convenience kits. The syringes have the potential for the plunger to draw back after the air has been expelled and reintroduced air back into the syringe. The air could then be inadvertently pushed into the patient's vascular system creating the potential for an air embolism which can result in serious adverse health consequences or death. These syringes were placed into the following lots of kits:

- 1 lot of AMS-9041CP Leaderflex Insertion Kit with Ultrasound
- 1 lot of AMS-9046CP-1 Insertion Tray-RX
- 45 lots of AMS8939A Universal Procedure Pack w/Split Drape
- 1 lot of AMS9957A Port Insertion Pack
- 3 lots of AMS12149 Procedure Pack

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/windstone-medical-packaging-dba-aligned-medical-solutions-issues-nationwide-recall-cardinal-healths?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.